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UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

United States of America Plaintiff, v. Seditious Vapours LLC, d/b/a Butt Out, a limited liability corporation, and Matthew D. Berger, an individual , Defendants.	Case No. 22-cv- **COMPLAINT FOR PERMANENT INJUNCTION** Date: October 18, 2022 Judge:

Plaintiff, the United States of America, by its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to permanently enjoin Seditious Vapours LLC ("Seditious Vapours"), an Arizona limited liability company d/b/a Butt Out, and Matthew D. Berger, an individual from violating 21 U.S.C. § 331(k), by causing tobacco products, within the meaning of 21 U.S.C. § 321(rr), to become adulterated and misbranded while they are held for sale after shipment of one or more of their components in interstate commerce.

Jurisdiction and Venue

2. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a), and personal jurisdiction over all parties.

3. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c).

Defendants

4. Seditious Vapours is an Arizona limited liability company with a registered office address at 3201 North 16th Street, Suite 14, Phoenix, AZ 85016, within the jurisdiction of this court. The company owns two locations in Phoenix from which it conducts its tobacco product operations: a manufacturing site at 3201 North 16th Street, Suite 14 ("North 16th Street facility") and a retail location at 708 East Virginia Avenue ("Virginia Avenue facility").

5. Matthew D. Berger is the sole employee and owner of Seditious Vapours, and the most responsible individual at the company. He is responsible for all manufacturing, ordering, and retail operations.

6. Defendant Berger performs his duties at the North 16th Street facility and the Virginia Avenue facility, within the jurisdiction of this Court.

Defendants' Operations

7. Defendants manufacture finished electronic nicotine delivery system ("ENDS") products, including finished e-liquids under the Butt Out brand, at the North 16th Street facility. Defendants' manufacturing activities include mixing, bottling, and labeling his ENDS products. Defendants sell and distribute their ENDS products to individuals for personal consumption at the Virginia Avenue facility and at a neighboring convenience store located at 702 East Virginia Avenue in Phoenix.

Defendants' ENDS Products Are Adulterated and Misbranded.

8. Defendants violate the Act by causing tobacco products to become adulterated and misbranded while they are held for sale after shipment of one or more of their components in interstate commerce. 21 U.S.C. § 331(k).

Defendants' ENDS Products Are Tobacco Products.

9. The Act defines "tobacco product" at 21 U.S.C. § 321(rr) to include "any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product." A "tobacco product" within the meaning of 21 U.S.C. § 321(rr) is generally subject to the requirements in 21 U.S.C. Chapter 9, Subchapter IX. See 21 U.S.C. § 387a(b) (providing that such subchapter shall apply to "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that [FDA] by regulation deems to be subject to this subchapter"); 81 Fed. Reg. 28974, 28975 (May 10, 2016) (deeming all products meeting the definition of "tobacco product" at 21 U.S.C. § 321(rr), except accessories of such newly deemed products, to be subject to such subchapter).

10. ENDS products generally meet the definition of "tobacco product" at 21 U.S.C. § 321(rr), and include: "devices, components, and/or parts that deliver aerosolized e-liquid when inhaled." FDA, Guidance for Industry: Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the

Market Without Premarket Authorization (Revised)* (Apr. 2020), 9–10, https://go.usa.gov/xuvn5. E liquids "are a type of ENDS product and generally refer to liquid nicotine and nicotine-containing e-liquids (i.e., liquid nicotine combined with colorings, flavorings, and/or other ingredients)." *Id.*

11. Defendants' ENDS products are made or derived from tobacco, or contain nicotine from any source, and are intended for human consumption, and thus are "tobacco product[s]" within the meaning of 21 U.S.C. § 321(rr).

Defendants' ENDS Products Are New Tobacco Products

12. The Act defines "new tobacco product" at 21 U.S.C. § 387j(a)(1) to include "any tobacco product . . . that was not commercially marketed in the United States as of February 15, 2007."

13. Defendants' ENDS products were not commercially marketed in the United States as of February 15, 2007, and thus are "new tobacco product[s]" within the meaning of 21 U.S.C. § 387j(a)(1).

Pathways to Market for New Tobacco Products

14. A new tobacco product may receive FDA marketing authorization through anyone of three pathways: (1) the premarket tobacco product application ("PMTA") pathway under 21 U.S.C. § 387j, through which FDA reviews a PMTA and issues an order permitting marketing of the new tobacco product ("MGO") under 21 U.S.C. § 387j(c)(1)(A)(i) upon a finding that the product is appropriate for the protection of the public health; (2) the substantial equivalence ("SE") pathway under 21 U.S.C. § 387j(a)(2)(A)(i), through which FDA reviews a report submitted under 21 U.S.C. § 387e(j) ("SE report") for the product and issues an order determining, among other things, that it is substantially equivalent to a tobacco product commercially marketed in the U.S. as of February 15, 2007, or a tobacco product marketed after that date, but which FDA previously determined to be substantially equivalent ("SE order"); or (3) the SE exemption pathway under 21 U.S.C. § 387j(a)(2)(A)(ii), through which

FDA reviews an exemption request submitted under 21 C.F.R. § 1107.1 and a report submitted under 21 U.S.C. § 387e(j)(1) ("abbreviated report") for the product, and issues a "found-exempt" order pursuant to 21 U.S.C. § 387e(j)(3)(A).

15. A new tobacco product that is required by 21 U.S.C. § 387j(a) to have premarket review and does not have an MGO in effect under 21 U.S.C. § 387j(c)(1)(A)(i), is adulterated under 21 U.S.C. § 387b(6)(A). A new tobacco product is required by 21 U.S.C. § 387j(a) to have premarket review, unless it has an SE order or found-exempt order in effect. See 21 U.S.C. § 387j(a)(2)(A).

16. A new tobacco product for which a "notice or other information respecting it was not provided as required" under the SE or SE exemption pathway, including an SE report or an abbreviated report, is misbranded under 21 U.S.C. § 387c(a)(6).

Defendants' ENDS Products Have Not Been Authorized by FDA and Are Both Adulterated and Misbranded

17. Defendants' ENDS products, as "new tobacco product[s]" within the meaning of 21 U.S.C. § 387j(a)(1), are required by 21 U.S.C. § 387j(a) to have premarket review, as they do not have an SE order or found-exempt order in effect. Defendants' ENDS products do not have an MGO in effect under 21 U.S.C. § 387j(c)(1)(A)(i). Accordingly, Defendants' ENDS products are adulterated under 21 U.S.C. § 387b(6)(A).

18. In addition, neither an SE report nor an abbreviated report has been submitted for any of Defendants' ENDS products. Accordingly, Defendants' ENDS products are misbranded under 21 U.S.C. § 387c(a)(6).

Defendants Engage in Interstate Commerce.

19. Defendants hold their ENDS products for sale after shipment of their components in interstate commerce. Specifically, Defendants use flavors from California to make their ENDS products.

Defendants' History of Violative Conduct

20. Defendants are aware that their practices violate the Act. FDA has repeatedly warned Defendants about their violative conduct and explained that continued violations could lead to enforcement action, including an injunction.

21. FDA sent Defendants a Warning Letter on August 27, 2021, after conducting a review of Seditious Vapours's website. The Warning Letter informed Defendants that they manufacture and offer for sale or distribution new tobacco products that lack required FDA authorization, including certain finished e-liquid products under the Butt Out brand. The Warning Letter further cautioned that such products are adulterated under 21 U.S.C. § 387b(6)(A) and misbranded under 21 U.S.C. § 387c(a)(6), and that failure to address these violations of the Act relating to tobacco products could lead to enforcement action, including an injunction.

22. On December 6, 2021, FDA held a teleconference with Defendant Berger regarding the violations cited in the Warning Letter. During the teleconference, Defendant Berger stated that Seditious Vapours had ceased selling e-liquid products on the company's website (https://buttoutecigs.com), but was unclear regarding whether corrective actions were taken for the products manufactured and sold at the company's brick-and-mortar locations. Defendant Berger initially stated that the company did not operate brick-and-mortar locations. When FDA stated that the company's website indicated that it sells tobacco products from a retail location, Defendant Berger stated that it did "a little bit." Defendant Berger stated that he only carried products manufactured by third-party brands in his store but did not answer when asked if he manufactures e-liquids under the Butt Out brand.

23. FDA inspected Defendants' North 16th Street facility and Virginia Avenue facility on March 29-30, 2022. During this inspection, FDA investigators observed that Defendants continued to manufacture, sell, and distribute new tobacco products, including finished e-liquid products under the Butt Out brand, that lacked required FDA

authorization, in violation of the Act. At the close of the inspection, FDA investigators discussed these violations with Defendant Berger and reminded him of his responsibility to ensure compliance with the Act and that failure to do so may lead to further enforcement action, including an injunction. In response, Defendant Berger told FDA investigators that he planned to continue to manufacture and sell Defendants' ENDS products and to discuss his options with "experts." Defendants have not contacted FDA since then.

Request for Relief

24. Despite numerous notifications, Defendants remain unwilling to comply with the Act. Unless restrained by this Court, Defendants will continue to violate the Act in the manner set forth above.

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with Defendants, from doing or causing a violation of 21 U.S.C. § 331(k), by causing tobacco products to become adulterated and misbranded while they are held for sale after shipment of one or more of their components in interstate commerce;

II. Order that FDA be authorized pursuant to this injunction to inspect Defendants' places of business, and all records relating to the manufacture, sale, and distribution of tobacco products, to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

III. Award Plaintiff its costs incurred in pursuing this action, including the costs of investigation to date, and such other equitable relief as the Court deems just and proper.

Respectfully submitted,

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